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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,477	01/14/2004	Anuja Nair	895,675-195	5834

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LEYDIG, VOIT & MAYER, LTD
TWO PRUDENTIAL PLAZA, SUITE 4900
180 N. STETSON
CHICAGO, IL 60601-6731

EXAMINER	
SHAHRESTANI, NASIR	

ART UNIT	PAPER NUMBER
3737	

NOTIFICATION DATE	DELIVERY MODE
03/09/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Chgpatent@leydig.com
Chgpatent1@leydig.com

Office Action Summary	Application No.	Applicant(s)	
	10/758,477	NAIR ET AL.	
	Examiner	Art Unit	
	NASIR SHAHRESTANI	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 13-34* is/are rejected.

7)☒ Claim(s) *12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/18/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 11/23/2009 have been fully considered but they are not persuasive. Applicant has argued that the prior art reference(s) (namely Rex), does not provide teachings of the claim language and that in contrast, "applicant's claimed catheter transfer function need not be rendered from backscattered signals *from within* a vascular structure...". Furthermore, applicant argues that "Rex's transfer function is the measure quantity (i.e. the desired output) of interest for further imaging analysis - as opposed to a signal component that needs to be removed from a received signal (e.g. applicant's catheter transfer function)".

Applicant is respectfully reminded that the intended invention should be present within the language of claim limitations. The language within the claim limitations does not provide any indication that the catheter transfer function need not be rendered from backscatter signals from within a vascular structure. Furthermore, there is not language that requires a signal component that needs to be removed from a received signal.

Examiner respectfully disagrees with applicant and maintains that the prior art of record substantially obviates presently submitted claim language.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-11, 13-16, 18-28, 30-34 are rejected under 35 U.S.C. 103(a) as being obvious over Vince et al. (U.S. 6,200,268 B1) in view of Rex (U.S. 6,038,468).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Vince et al. teach a catheter (fig. 1) comprising at least one transducer (element 20) as well as a computing device (col. 4 lines 5-7). Vince et al. teach an ultrasonic method and system for characterizing plaque components within a vascular object (see abstract). Vince et al. further teach inserting at least a portion of a catheter into a vascular structure (col. 3 line 55); activating a transducer portion (col. 3 line 57), said activation of said transducer resulting in an ultrasound signal begin transmitted toward vascular tissue and acquiring backscatter ultrasound data from said vascular tissue (col. 3 lines 57-59).

As applicant has stated (page 2/13 under Description of Related Art), traditionally the transfer function (being estimated in the Vince et al. reference) has been determined with the catheter outside of the patient however Vince et al. do not teach the estimation of a transfer function of the inserted catheter.

Rex teaches an ultrasonic catheter localization system (see title and abstract) wherein a transfer function may be determined for each acoustic signal, once reflections of the acoustic signal from the wall of the part of the body in which the catheter head is disposed are received (col. 2 lines 7-14). With regards to claims 3 and 18, Rex further teaches providing an iterative process of model fitting (col. 2 line 25).

It would have been obvious to one of ordinary skill in the art at the time of invention to have modified Vince et al. and to have incorporated the teaching of Rex, providing the estimation of the transfer function of the inserted catheter, so that a further and more precise step of catheter localization can be achieved from backscatter data received within the vascular wall of the patient.

Regarding claims 4-6 and 19, Vince et al. further teach correction of backscatter data and wherein in order to accurately match coordinates of images, the histological image is warped to fit the contour of the IVUS image (col. 4 lines 10-32).

Regarding claims 7, 8, 11, 21, 26, 32-34, Vince et al. further teaches final signal parameters corresponding to the plaque component within a region of interest which represents the plaque content from the histology region of interest are stored in a look up table or database and correlated/characterized to the plaque content (figs. 6A and 6B) which also shows performing a fast Fourier transform of signal segments (transformation from time domain to frequency domain) and the identification/display of the segments (A1 and B1) using a database adapted to store a plurality of parameters corresponding to a plurality of vascular tissue types (see Vince et al. claim 7) and a method of characterizing a plaque component (Vince et al. claim 16).

With regards to claims 9 and 22, Vince et al. further teach that additional analysis can be performed such as spectral density and/or power spectrum analysis to provide more information regarding the signal (col. 5 lines 10-14).

Regarding claims 10 and 23, Vince et al. show that the types of plaque components which may be found in a blood vessel include collagen, calcium, necrotic areas, lipids and cholesterol (col. 4 lines 22-24).

With regards to claims 12, 16, and 25, the limitations of the claims are merely providing a duplication and repetition of the method of claim 1 and no additional structure to claim 13 and are hence an obvious addition to the method of calculation in order to provide further backscatter

ultrasound data of the vasculature. As described before, Rex teaches an algorithm/application to calculated response data with regards to a transfer function.

With regards to claims 20, 30, 31, Vince et al. further teach the ultrasonic device may also be an array of transducers circumferentially positioned to cover 360 degrees where each transducer radially acquires radio frequency data from a fixed position (col. 3 lines 50-53).

Regarding claim 24, Vince et al. show that the histology image shoes different tissue types with different colors which are identifiable by a trained operator (col. 4 lines 20-22).

Claims 2, 17, 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vince et al. in view of Rex as applied to claims 1, 13 and 26 above, and further in view of Sieben (U.S. 5,445,155).

Vince et al. in view of Rex teach all the limitations of claims 1, 13 and 26 but do not specifically address a step filtering noise from backscattered ultrasound data.

It would have been obvious to one of ordinary skill in the art at the time of invention to have modified Vince et al. in view of Rex and to have provided the filtering of noise in ultrasound data, being well-known in the art and exemplified by Sieben (col. 14 lines 13-25), wherein a method is employed to improve signal-noise ratio, hence providing clearer data.

Allowable Subject Matter

Claim 12 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record does not teach nor fairly suggest repositioning a portion of the catheter to a second location for acquiring echoes from a second portion of vascular tissue, calculating a second response data using a second transfer function, the response data being indicative of data that is backscattered and independent from data modifications resulting from the catheter.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NASIR SHAHRESTANI whose telephone number is (571)270-1031. The examiner can normally be reached on Mon.-Thurs: 7:30-5:00, 2nd Friday: 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRIAN CASLER/
Supervisory Patent Examiner, Art Unit 3737

/Nasir Shahrestani/
Examiner, Art Unit 3737